UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 29, 2005

MEMORANDUM

Subject: Efficacy Review for Hype-Wipe®, EPA Reg. No. 70590-1;
DP Barcode: D316414

From: Marcie Wawzysko Tidd, Microbiologist Marcie Tidd 6/29/2005
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Applicant: Current Technologies, Inc.
P.O. Box 21
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Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	0.94%
Other ingredients	99.06%
Total	100.00%

I. BACKGROUND

The product, Hype-Wipe®, is an Agency registered (Reg. No. 70590-1) disinfectant (bactericide and tuberculocide) impregnated wipe product developed by Current Technologies, Inc. The applicant wishes to revise their product label to add a disinfectant claim against *Clostridium difficile*. The submitted study was conducted at MicroBio Test, Inc. located at 105B Carpenter Drive in Sterling, VA.

The data package contained a letter from the applicant to the Agency (dated January 10, 2005), EPA Form 8570-1 (Application for Pesticide), one study (MRID No. 464425-01), and the proposed product label.

II. USE DIRECTIONS

This product is an impregnated wipe intended for use as a disinfectant on hard non-porous surfaces in areas such as laboratories, hospital areas, blood banks, ambulances, nursing homes, veterinarian facilities, wastewater facilities, and restrooms. The product is intended for use on materials such as stainless steel, plastics, glass, glazed ceramics, tile, linoleum, laminated plastic countertops, enamel, vinyl, and glazed porcelain. The proposed product label give the following instructions for the use of the prod cut as a disinfectant: Remove gross filth and heavy soil from surfaces. Open pouch, remove towel. Use towel and excess liquid to wipe surface. Allow solution to contact surface for 2 minutes to inactivate a broad range of organisms before wiping or allow to air dry.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in disinfecting hard surfaces. The standard test methods available for hard surface disinfectants (i.e., AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method), if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the AOAC Germicidal Spray Products as Disinfectants Method. In place of spraying the inoculated surface of the glass slide, the product should be tested by wiping the surface of the glass slide with the saturated towelette, and then subculturing the slides after a specified holding time. Remaining liquid should be expressed from the used towelette and subcultured. Sixty carriers must be tested with each of 3 towelettes from freshly opened packages, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). The towelette should be removed from its container and subsequently handled with sterile gloves. One towelette should be used

to wipe at least 60 inoculated slides. To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. In addition, subcultures of the liquid expressed from the used towelettes should be negative for growth. These Agency standards are presented in DIS/TSS-1 and EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes.

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, but not including viruses, must also be determined by the modified version of the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers (for both the slide subculture and the expressed liquid from the towelette) is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-01.

IV. SUMMARY OF SUBMITTED STUDIES

MRID 464425-01 "Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Against *Clostridium difficile* for Hype-Wipe" by Angela L. Hollingsworth. Study conducted by MicroBio Test, Inc. – Study/Project ID Number 504-117. Study completed October 26, 2004.

This study was conducted against *Clostridium difficile* (ATCC 9689). Two lots (Lot Nos. 101204HA and 101204HB) were tested according to MicroBio Test protocol 504.2.10.11.04 (copy provided). The wipe product was received ready-to-use. Heat-inactivated horse serum was added to the inoculum to achieve a 5% organic load. Aliquots of 0.01-0.03 mL of the culture were added to ten sterile glass carriers per product lot and spread with a sterile glass rod. Carriers were dried for 20-40 minutes at 37±2C. Each glass slide carrier was wiped 3 times from right to left with one such motion being considered one stroke. The same carrier was then wiped up to down three strokes. One towelette was used to treat 10 carriers. Following a 1 minute contact time at room temperature, carriers were transferred to individual tubes containing 20 mL of reinforced clostridial medium containing 0.1% sodium thiosulfate and shaken. After treatment, some of the liquid remaining in the wipes was expressed and a 0.1 mL aliquot was cultured into 20 mL of the neutralizer. All neutralized tubes were incubated for 48±2 hours at 37±2C and observed for the presence or absence of growth. Controls included those for viability, carrier count, neutralizer effectiveness, sterility, bacteriostasis, and confirmation of the challenge organism.

V. RESULTS

MRID Number	Organism	Avg. CFU/Carrier	Lot Number	Carrier Results in Tubes with Growth/Total Tubes	Express Liquid Results in Tubes with Growth/Total Tubes
464425-01	*Clostridium difficile*	4.9×10^4	101204HA	0/10	0/1
			101204HB	0/10	0/1

VI. CONCLUSIONS

The submitted data (MRID No. 464425-01) support the use of the product, Hype-Wipe®, as a disinfecting towelette against vegetative cells of *Clostridium difficile* (ATCC 9689) on hard, non porous surfaces for a contact time of one minute at room temperature in the presence of organic soil. No growth was seen in any of the 10 cultures of the slides for either product lot. Cultures of the expressed liquid showed no growth. Appropriate controls were in place and performed as expected.

VII. RECOMMENDATIONS

The proposed label claims that the product, Hype-Wipe®, is an effective one-step disinfectant against *Clostridium difficile* on hard, non porous surfaces in one minute. This claim is partially acceptable.

The applicant must indicate on the label that the product is effective against "vegetative cells of *Clostridium difficile*". This serves to clarify that the product is not a sporicide and will not be efficacious against spores of *C. difficile*. This change is to be made on pages 1 and 2 where *C. difficile* is printed.